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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Martin Purpura

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EXAMINER

MAEWALL, SNIGDHA

ART UNIT

PAPER NUMBER

1612

MAIL DATE

DELIVERY MODE

08/13/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/511,884	Applicant(s) PURPURA ET AL.	
	Examiner Snigdha Maewall	Art Unit 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 June 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-34 is/are pending in the application.
- 4a) Of the above claim(s) 1-14 and 32-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>05/04/05 and 06/02/09</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Summary

1. Receipt of IDS filed on 05/04/05 and 06/02/09 is acknowledged.

Restriction/Election

Applicant's election of group I, claims 15-31 in the reply filed on 06/02/09 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 32-34 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 06/02/09.

Claims 15-31 are under prosecution.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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3. Claims **15-31** are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 15 recite the various components that provide stable matrix, however no specific recitation of carbohydrate, polymer mineral etc. has been cited in the claims. The claims recite various components as supporting material, however no specific components are disclosed. Due to the lack of specific ingredients the structural and functional relation cannot be deduced. In order to provide meaningful search, the examiner suggests specifying individual components which are responsible for specific function claimed.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 15-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The 15 recites the limitation as $\geq 5\%$ by weight acetone insoluble phospholipid components based on a starting material of the acetone insoluble phospholipid components as a bioactive agent which makes the claim indefinite. It is not clear what ingredients are claimed in starting material and in what amount. There are various

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phospholipids which are acetone insoluble, therefore it is not clear which phospholipid is the applicant claiming. The metes and bounds of claim are not defined. For meaningful search, the examiner suggests reciting specific ingredients with specific amounts. The word stable is not clear, stable in what sense? Claim 25 recites the limitations polyphenols, trace elements, suitable derivatives and mineral substances which make the claim indefinite metes and bounds of claims are not defined. Appropriate correction is required.

DOUBLE PATENTING

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 15-31 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11, 13-21

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and 23-37 of copending Application No. 10/511885. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of copending application and instant application have overlapping subject matter. The only difference is in particle size of instant application. Since the copending claims are also matrix, one would expect some particle size in copending application and optimization to the claimed size is a parameter which can be optimized.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this

Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 15-18 and 20-30 are rejected under 35 U.S.C. 102(e) as being

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anticipated by Friedman (US pg pub 2003/0021881).

Friedman discloses homogeneous solid matrix containing proteins and lecithin, see abstract and examples. The reference teaches solid matrix of various shapes for administration of ingestible bioactive compounds, the composition has improved gastrointestinal dissolution and oral availability, see page 2, paragraph [0023]. The composition teaches lecithin (which is also known in the art as phosphatidylcholine), triglycerides and soybean, see page 2, paragraph [0092-0094] and 0078,. The reference teaches silica in the composition, paragraph [0046] and vitamins and tocopherol in paragraph [0197]. Example 9 discloses fatty alcohol and lipid. The reference teaches polysaccharides in the composition, see paragraph [0012]. The amount of soybean lecithin is 0.5 gm to 1 gm in examples 19 and 20 which is more than 5% in the examples. The reference teaches utilizing wet granulation method for processing and extruding through the screen having openings of 0.5mm to 2.5mm and spheronized in a spheronizer, see paragraph 005.

It is to be noted that instant specification describes that phospholipids are typically insoluble in acetone which is why they are also referred to as acetone-insoluble phosphatides or substances and on page 1, therefore prior arts lecithin which is a phospholipid reads on the claimed component.

Claim Rejections - 35 USC § 103

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9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 15-18 and 20-31 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Kiliaan et al. (WO 01/84961 A2) in view of Friedman (US pg pub 2003/0021881).

Kiliaan et al. discloses a nutritional preparation suitable for the prevention and/or treatment of vascular disorders, comprising the following fractions: fraction a) long chain polyunsaturated fatty acids; fraction b) phospholipids, the fraction contains at least two different phospholipids selected from the group consisting of phosphatidylserine, phosphatidylinositol, phosphatidylcholine and phosphatidylethanolamine, fraction c) compounds which are a factor in methionine metabolism, which fraction contains at least one member selected from the group consisting of folic acid, vitamin B 12, vitamin B6, magnesium and zinc (abstract). The preparation of the invention can be a pharmaceutical, dietetic as well as a nutritional preparation. The products can have the form of a liquid, powder, bar, cookie, sweetie, concentrate, paste, sauce, gel, emulsion, tablet, capsule, etc. to provide the daily dose of the bioactive components either as a single or in multiple doses (page 6, lines 1-5). Triglyceride is listed on page 6, line 14. The composition contains zinc and copper (see page 9, lines 1-5). Kiliaan et al. discloses on page 12, various diseases and symptoms that can be treated are cognitive

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degeneration and improper functioning associated with kidneys, liver, stomach etc.

Another advantage of the composition disclosed is in normalizing plasma cholesterol levels (see page 6, lines 17-18). Kiliaan discloses a capsule containing phospholipid comprised of phosphatidyl serine and phosphatidyl choline; the composition also contains DHA and EPA omega fatty acids, vitamin, coenzyme Q10, folic acid as described in Example 1; phosphatidyl choline at 15.6% and phosphatidyl serine 14.4% and 15.1% of the composition is the omega fatty acids. The composition of Kiliaan is administered to treat vascular disorders. The reference teaches that the composition can be in the form of tablet, powder, bar cookie or capsule, see page 6, lines 1-5.

While Killian teaches nutritional preparation can be in a tablet form, Killiaan does not teach the claimed particle size. Friedman as discussed above, teaches a nutritional preparation comprising solid matrix with particle size from 0.5mm to 2.5 mm (500 micrometer to 2500 micrometer) and discloses that the composition has improved gastrointestinal dissolution and oral availability, see page 2, paragraph [0023].

It would have been obvious to one of ordinary skill in the art at the time of instant invention to have prepared the nutritional preparation of Killian et al. comprising particle size in the range of 500 micrometer to 2500 micrometer for better dissolution and oral availability motivated by the teachings of Freidman et. al.

11. Claim 19 is rejected under 35 U.S.C. 103 (a) as being unpatentable over Kiliaan et al. (WO 01/84961 A2) in view of Friedman (US pg pub 2003/0021881) and further in view of Ponroy (USP 6,069,138).

The references taught above do not disclose Sphingomyelin in the nutritional preparation.

Ponroy teaches use of phospholipids in therapy and dietetic composition, see abstract. The reference teaches importance of a composition comprising various phospholipids such as phosphatidylserine, phosphatidylcholine, sphingomyelin and lysophospholipids in improving the quality of nighttime sleep, alertness during the day as well as memory and learning skills, see column 3, lines 14-20 and examples in column 3 and 4.

It would have been obvious to one of ordinary skill in the art at the time of instant invention to incorporate lysophospholipid or sphingomyelin in the nutritional preparation of Killian and Freidman for therapeutic benefits such as memory and learning capabilities associated with various phospholipids as taught by Ponroy's reference.

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12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Snigdha Maewall whose telephone number is (571)-272-6197. The examiner can normally be reached on Monday to Friday; 8:30 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-0580. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Snigdha Maewall/

Examiner, Art Unit 1612

/Gollamudi S Kishore/

Primary Examiner, Art Unit 1612